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Supplementary Table 1. Practical Considerations: Informed Consent

Elements to Include	**Research Needs**	**Sample Language**
Purpose	The purpose and goals of the study should be explained clearly and simply. The study participants should understand why their biosample is needed and what knowledge can be gained from providing it. If the specific genes to be examined are known (e.g. *CYP2A6*) then the purpose stated should be specific to those genes. See sample language on the right.	"We would like to explore how genetic variation among people receiving nicotine patches alters their response to treatment. We can determine if your ability to break down nicotine is normal, fast, or slow by looking at your DNA".
	However, sometimes it is not clear at the time of sample collection what the specific genes of interest might be. In the case, consent needs to be given to study other genes of interest, or other chemical modifications, e.g., methylation. See sample language on the right.	"We will also look at your DNA to see if we can find other changes that may affect your ability to quit smoking."
	To enable future molecular analyses other than on the same analyte (e.g., peripheral blood derived DNA for genotyping/sequencing and methylation analyses), e.g., metabolomics, to study nicotine metabolites, pharmacotherapy metabolites, or other metabolites as markers of functional variants, additional language will be needed. For metabolomics of tobacco, pharmacotherapy and common metabolites. See sample language on the right.	"We may also be interested in analyzing metabolism of nicotine and other tobacco smoke constituents, of smoking cessation pharmacotherapies, and of common metabolites, for the purpose of understanding the influence of functional variants and modifications on tobacco smoke, pharmacotherapy and common metabolites, which vary among smokers, participants attempting smoking cessation and all individuals."
Risks and Benefits	There are no physical risks of providing a saliva sample. However, if a blood sample is going to be taken then the consent form should outline the risks of venipuncture (possible bruising). The biggest risk of genetic research is the possibility of disclosure of study participation or research results to individuals not involved in the study, such as insurers or employers. The participant needs to be assured that the research team will take all reasonable steps to protect their research information in order to minimize the potential of harm to you from an unintended disclosure of genetic or clinical information. They should also be	"In the event that you suffer injury as a direct result of participating in this study, normal legal rules on compensation will apply. By signing this consent form, you are in no way waiving your legal rights or releasing the investigators from their professional and legal responsibilities."

	informed that signing the consent does not waive their legal rights to seek compensation if they are harmed as a result of their participation in the study. See sample language on the right.	
Confidentiality	Participants need to know that their genetic information will not be shared with anyone not directly involved in the research. See sample language on the right.	"We will not give your genetic results to anyone, unless required by law. "Anyone" includes you, your family, your insurance company, and your employer. Your genetic results are for research purposes only and have no established use for clinical diagnosis or treatment. Although your sample and information are coded, we cannot guarantee that a connection between you and your results will not be established".
	The consent form should outline the steps that will be taken to ensure that their genetic information will be anonymized. See sample language on the right.	"To protect your information, you will be assigned a study code. This number will be used to keep track of your samples and medical information. All information that we collect from you and the results from your sample analysis will not identify you in any way. The file containing the link between the study code and your name will be stored on a secure server and will be password protected. Only the study investigators and delegates will have access to this file".
	Participants need to be assured that their identity will not be divulged by the investigators. See sample language on the right.	"Your name will not appear in any publications or external reports about this research. Also, your medical information and any coded results will be entered on a computer and stored in an electronic database on an encrypted server. We will comply with the relevant laws to protect the confidentiality of research participants when processing and storing personal information".
	If there is a possibility that other researchers or companies may have access to the biosamples or the data generated the participants need to be informed of that possibility. See sample language on the right.	"We may collaborate with other research organizations in other locations, including commercial companies, who may want to use your sample and already collected medical information for studying genetic material and substances related to research on addictive or psychiatric disorders. Your name or any other information that could identify you will not be released. We will require that other collaborators keep your anonymized medical information confidential".
Data sharing	If the biological samples will be	"We will share your blood and data with

	deposited to a data repository the participants need to be informed of that possibility. See sample language on the right.	other researchers. They may be doing research in areas similar to this research or in unrelated areas. These investigators may be at XX University or at other research centers. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval form individuals that monitor the use of the data, will be able to look at your information. To ensure other investigators receiving the blood and data will not have your name or any other kind of link that would identify you, we maintain and securely store your blood and data and the link to your identity through a random identification number which is different from your study identification number."
Sample and Information Storage and Destruction	The procedures for storage and eventual destruction of the biosample and the data need to be made explicit. Details on how long the sample will be kept for and where the data will be stored and for how long need to be provided. See sample language on the right.	"We will work with and store your sample securely for xx years after which time it will be destroyed by [insert method]. As part of government regulations we are required to keep and archive all research records for a period of xx years after which they will be securely shredded and destroyed."
	Participants need to be aware that they can change their mind regarding their participation in the study and that their DNA sample will be destroyed if that is what they want. Different Institutional Review Boards may have different requirements regarding this. See sample language on the right.	"Taking part in this study is entirely voluntary. You may decide not to take part or you may decide to take part and then change your mind. You can withdraw from this study at any time without giving a reason. Also, it will not affect your access to current or future treatment at this institution. If you withdraw from this study, your DNA sample will be destroyed. However, we will keep any genetic results and clinical information collected up to that point".